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EXAMINER

TANNER, JOCELIN C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,429	Applicant(s) CARREZ ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This Office Action is in response to the Amendment filed 29 June 2009. Claims 1-9 are currently pending. The Examiner acknowledges the amendments to claim 1.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 1, it is unclear from what and how the retention device is unconstrained while mounted to tilt in the cage around a pivoting axis. It is unclear from what the retention device is unconstrained since the instant application is prevented from reverse tilting via a tongue compressed by a wall of the cage and the prior art reference is prevented from reverse tilting by a spring.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Plassche, Jr. (US Patent No. 5,300,045).**

Regarding claim **1**, Plassche, Jr. discloses a cannula (80) including a short tubular catheter (82) with a base, including a needle (90) having a skin-puncture end (114), an anti-prick cage (96) forming a chamber (98) through which the needle slides to a distal exit, a trap (110) to hold the puncture end of the needle in the chamber when the needle is withdrawn, having retention resources including an external rim (118) formed on the base and an external dog (120) held by the rim and provided on the cage wherein the retention device (106) is mounted to tilt in the cage around a pivoting axis transverse to the sliding direction of the needle and the dog lifts and releases itself from the rim to position itself in front of the puncture end to prevent the end from exiting the chamber (column 6, lines 13-19, 28-37, 44-53, Fig. 15).

2. Regarding claim **2**, Plassche, Jr. discloses the claimed invention except for the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end. It would have been an obvious matter of design choice to construct the retention device having the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end, since applicant has not disclosed that having the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with having the weight distributed in a form required to sufficiently create a pivoting device.

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3. Regarding claims **3 and 7**, Plassche, Jr. discloses lateral nipples (108) formed on the retention device and accommodated within a cradle created by cut-outs in two opposite walls of on the cage (Fig. 15).

4. Regarding claims **4 and 8**, Plassche, Jr. discloses a cradle that is capable of being placed within the housing by clickon action.

5. Regarding claims **5 and 9**, Plassche, Jr. discloses a flexible tongue (116) that is capable of being held compressed elastically by a wall of the cage (96) when the device (106) is held by the needle (90) wherein the tilting of the device in the reverse direction is prevented by trapping the tongue under the wall (Figs. 15 and 17).

6. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaba (US Patent No. 5,697,907).

Regarding claim **1**, Gaba discloses a cannula including a short tubular catheter (222) with a base, including a needle (132) having a skin-puncture end (135), an anti-prick cage (320) forming a chamber through which the needle slides to a distal exit, a trap (318) to hold the puncture end of the needle in the chamber when the needle is withdrawn, having retention resources including an external rim (232) formed on the base and an external dog (314) held by the rim and provided on the cage wherein the retention device (302) is mounted to tilt in the cage around a pivoting axis transverse to the sliding direction of the needle and the dog lifts and releases itself from the rim to position itself in front of the puncture end to prevent the end from exiting the chamber (column 5, lines 17-39 Figs. 10-12).

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7. Regarding claim **2**, Gaba discloses the claimed invention except for the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end. It would have been an obvious matter of design choice to construct the retention device having the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end, since applicant has not disclosed that having the weight of the part of the device located between the pivoting axis and the retention end is less than the weight of the part of the device located between the axis and the contact end solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with having the weight distributed in a form required to sufficiently create a pivoting device.

8. Regarding claims **3 and 7**, Gaba discloses lateral nipples (310) formed on the retention device and accommodated within a cradle created by cut-outs in two opposite walls of on the cage (column 5, lines 3-5, Figs. 10-12).

9. Regarding claims **4 and 8**, Gaba discloses a cradle that is capable of being placed within the housing by clickon action.

10. Regarding claims **5 and 9**, Gaba discloses a flexible tongue (260, 264) that is capable of being held compressed elastically by a wall of the cage (320) when the device (302) is held by the needle (132) wherein the tilting of the device in the reverse direction is prevented by trapping the tongue under the wall (Figs. 10 and 11).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Plassche, Jr. (US Patent No. 5,300,045) in view of Purdy et al. (US Patent No. 5,215,528).

13. Regarding claim 6, Plassche, Jr. fails to disclose retention resources that that prevent the puncture end of the needle from leaving the cage via the proximal entrance of the chamber.

Purdy et al. teaches a device having a needle tip shield wherein the needle (14) includes an enlarged diameter portion (14c) to prevent the needle from being fully withdrawn from the needle tip cover and being exposed (column 4, lines 28-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Plassche, Jr. with retention resources, as taught by Purdy et al., to prevent the needle from being fully withdrawn from the cage and to provide a seal between the catheter and the needle shaft.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaba (US Patent No. 5,697,907) in view of Purdy et al. (US Patent No. 5,215,528).

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15. Regarding claim 6, Gaba fails to disclose retention resources that that prevent the puncture end of the needle from leaving the cage via the proximal entrance of the chamber.

Purdy et al. teaches a device having a needle tip shield wherein the needle (14) includes an enlarged diameter portion (14c) to prevent the needle from being fully withdrawn from the needle tip cover and being exposed (column 4, lines 28-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Gaba with retention resources, as taught by Purdy et al., to prevent the needle from being fully withdrawn from the cage and to provide a seal between the catheter and the needle shaft.

Response to Arguments

16. Applicant's arguments filed 29 June 2009 have been fully considered but they are not persuasive. The Applicant contends that both Plassche and Gaba disclose a system including a lever constrained by a spring against the shank of the needle or a tensioned spring that pushes the lever which is in contrast to the instant application. However, the retention device of the instant application is mounted to tilt unconstrained in the same manner as the prior art. The instant application includes a tongue (6d) that deploys under the lateral wall of the cage (5), preventing reverse tilting of the device. The springs of Plassche and Gaba work to prevent reverse tilting of the device as well, Therefore, the retention devices of Plassche and Gaba are both mounted to tilt unconstrained in the cage around a pivoting axis. The Examiner inadvertently included a secondary reference in claim 1 of Gaba. Please disregard.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
10/05/2009
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/08/09